This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

CLAIMS

15

- 1. Dialysis machine comprising:
- a filter (4) having a blood compartment (5) and a dialysis liquid compartment (6) separated by a semi-permeable membrane (7);
- an extracorporeal blood circuit having an arterial pipe (12) connected to an inlet of the blood compartment (5) and a venous pipe (15) connected to an outlet of the blood compartment (5);
- a dialysis liquid circuit having a supply pipe (17)

 10 connected to an inlet of the dialysis liquid compartment (6)

 and a drain pipe (18) connected to an outlet of the dialysis

 liquid compartment (6);
 - an infusion circuit having a pre-dilution pipe (25) connected to the arterial pipe (12) and a post-dilution pipe (26) connected to the venous pipe (15);

characterized in that it comprises:

- means (23, 24) for varying the flow of an infusion liquid in the pre-dilution pipe (25) and in the post-dilution pipe (26), and
- control means (31) for controlling the flow varying means (23, 24) so that the flow of the infusion liquid in the pre-dilution pipe (25) and the post-dilution (26) pipe matches a determined sequence.
- 2. Dialysis machine according to claim 1, characterized in that the control means (31) comprises means for determining the infusion sequence from at least one characteristic value

WO 01/76661

(FF, TMP_{ave} , K_{uf}) correlated with the concentration of the blood (CE) and/or the filtration efficiency of the filter (4).

3. Dialysis machine according to claim 2, characterized in that the control means (31) comprises means for comparing the characteristic value (FF, TMPave, Kuf) with a series of intervals (I1...x, IT1...x, IK1...x), each interval (I1...x, IT1...x, IK1...x) being associated with at least a predetermined control signal (S, G, H, L).

10

- 4. Dialysis machine according to claim 3, characterized in that the infusion varying means comprises a valve means (24) for alternately occluding the pre-dilution pipe (25) and the post-dilution pipe (26), and in that the predetermined control signal (G) defines a sequence for opening and closing the valve means (24).
- 5. Dialysis machine according to one of the claims 3 and 4, characterized in that the infusion varying means comprises 20 an infusion pump (23) for circulating the infusion liquid, and in that the predetermined control signal (L) is for regulating the flow rate (IR) of liquid generated by the infusion pump (23).
- 6. Dialysis machine according to one of the claims 3 to 5, characterized in that it comprises a ultrafiltration pump (21) for causing ultrafiltration of plasma water through the membrane (7) of the filter (4), and in that the predetermined

control signal (S) is for regulating the flow rate (UFR) of liquid generated by the ultrafiltration pump (21).

- 7. Dialysis machine according to one of the claims 3 to 6, characterized in that it comprises a bubble trap (14) connected to the arterial pipe (12) and a bubble trap (16) connected to the venous pipe (15) and means (27, 28) for injecting or withdrawing air into/from the bubble traps (14, 16) so as to adjust the level of liquid therein, and in that the predetermined control signal (S) is for controlling the means (27, 28) for injecting or withdrawing air into/from the bubble traps (14, 16).
- 8. Dialysis machine according to one of the claims 2 to 7, characterized in that it comprises:
 - means for determining a ultrafiltration flow rate (UFR) of plasma water through the membrane (7) of the filter (4);
 - means (11) for determining the haematocrit (Hct) at the inlet of the filter (4), and
- means (31) for calculating the characteristic value as a filtration factor (FF) equal to UFR/[Qb(1-Hct)].
- 9. Dialysis machine according to claim 8, characterized in that the means for determining the haematocrit (Hct) comprises means for determining the haemoglobin concentration (11) at the inlet of the filter (4) and means (31) for dividing the haemoglobin concentration by a constant coefficient.

- 10. Dialysis machine according to one of the claims 2 to 7, characterized in that it comprises:
- means (32, 33) for measuring the blood pressure values (Pbo, Pbi) at the inlet and at the outlet of the blood compartment (5) of the filter (4);
- means (34, 35) for measuring the dialysis liquid pressure values (Pdi, Pdo) at the inlet and at the outlet of the dialysis liquid compartment (6) of the filter (4);
- means (31) for calculating an inlet transmembrane pressure value (TMP_i) as the difference between the pressure value (Pb_i) at the inlet of the blood compartment (5) and the pressure value (Pd₀) at the outlet of the dialysis liquid compartment (6) and an outlet transmembrane pressure value (TMP₀) as the difference between the pressure value (Pb₀) at the outlet of the blood compartment (5) and the pressure value (Pd_i) at the inlet of the dialysis liquid compartment (6);
 - means (31) for calculating the characteristic value as a mean transmembrane pressure value (TMPave) equal to [TMPi-TMPo]/2.

- 11. Dialysis machine according to claim 10, characterized in that it comprises:
- means for determining a ultrafiltration flow rate (UFR) of plasma water through the membrane of the filter (4);
- means (31) for calculating the characteristic value as an actual permeability (Kuf) equal to the ratio between the ultrafiltration flow rate (UFR) and the mean transmembrane pressure value (TMPave).

- 12. Method for infusing an infusion liquid in an extracorporeal blood circuit of a dialysis liquid machine, the extracorporeal blood circuit having an arterial pipe (12) connected to an inlet of a blood compartment (5) of a filter (4), and a venous pipe (15) connected to an outlet of the blood compartment (5), the filter (4) having a blood compartment (5) and a dialysis liquid compartment (6) separated by a semi-permeable membrane (7),
- 10 characterized in that it comprises the steps of;
 - determining an infusion sequence from at least one characteristic value (FF, TMP_{ave} , K_{uf}) correlated with the concentration of the blood (CE) and/or a filtration efficiency of the filter (4), and
- infusing the infusion solution in either one or both of the arterial pipe (12) and the venous pipe (15) in accordance with the determined infusion sequence.
- 13. Method according to claim 12, characterized in that it comprises the step of comparing the characteristic value (FF, TMPave, Kuf) with a series of intervals (I1...x, IT1...x, IK1...x), each interval (I1...x, IT1...x, IK1...x) being associated with at least a predetermined control signal (S, G, H, L).

25

14. Method according to claim 13, characterized in that the predetermined control signal (G) defines a sequence for opening and closing a valve means (24) arranged for

alternately occluding a pre-dilution infusion pipe (25) connected to the arterial line (12) and a post-dilution infusion pipe (26) connected to the venous line (15).

- 15. Method according to one of the claims 13 and 14, characterized in that the predetermined control signal (L) is for regulating the flow rate (IR) of liquid generated by an infusion pump (23) for circulating the infusion liquid
- 16. Method according to one of the claims 13 to 15, characterized in that predetermined control signal (S) is for regulating the flow rate (UFR) of liquid generated by a ultrafiltration pump (21) for causing ultrafiltration of plasma water through the membrane of the filter (4).

15

- 17. Method according to one of the claims 13 to 16, characterized in that the predetermined control signal (S) is for controlling means (27, 28) for injecting or withdrawing air into/from bubble traps (14, 16) respectively connected to the arterial pipe (12) and to the venous pipe (15).
- 18. Method according to one of the claims 12 to 17, characterized in that it comprises the steps of:
- determining a ultrafiltration flow rate (UFR) of plasma
 25 water through the membrane (7) of the filter (4);
 - determining the haematocrit (Hct) at the inlet of the filter (4), and
 - calculating the characteristic value as a filtration factor (FF) equal to UFR/ $[Q_b(1-Hct)]$.

15

- 19. Method according to claim 18, characterized in that the step of determining the haematocrit (Hct) comprises the step of determining the haemoglobin concentration at the inlet of the filter (4) and the step of dividing the haemoglobin concentration by a constant coefficient.
- 20. Method according to one of the claims 12 to 17, characterized in that it comprises the steps of:
- measuring the blood pressure values (Pbo, Pbi) at the inlet and at the outlet of the blood compartment (5) of the filter (4);
 - measuring the dialysis liquid pressure values (Pdi, Pdo) at the inlet and at the outlet of the dialysis liquid compartment (6) of the filter (4):
 - calculating an inlet transmembrane pressure value (TMPi) as the difference between the pressure value (Pbi) at the inlet of the blood compartment (5) and the pressure value (Pdo) at the outlet of the dialysis liquid compartment (6) and an outlet transmembrane pressure value (TMPo) as the difference between the pressure value (Pbo) at the outlet of the blood compartment (5) and the pressure value (Pdi) at the inlet of the dialysis liquid compartment (6);
- calculating the characteristic value as a mean
 transmembrane pressure value (TMP_{ave}) equal to [TMP_i-TMP_o]/2.
 - 21. Method according to claim 20, characterized in that it comprises the steps of:

- determining a ultrafiltration flow rate (UFR) of plasma
 water (7) through the membrane of the filter (4);
- calculating the characteristic value as an actual permeability ($K_{\rm uf}$) equal to the ratio between the ultrafiltration flow rate (UFR) and the mean transmembrane pressure value (TMPave).